510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k050328

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Quality Control Material for Human Chorionic Gonadotropin in urine.

D. Type of Test:

Not applicable

E. Applicant:

Biochemical Diagnostics, Inc.

F. Proprietary and Established Names:

Proprietary: Pregnancy-Skreen™

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1660; Quality Control Material (assayed and unassayed)

2. Classification:

   Class I

3. Product code:

   JJX; single (specified)

4. Panel:

   75; Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The Biochemical Diagnostics, Inc. Pregnancy-Skreen™ controls are controls intended to validate the performance of qualitative hCG methods. They should be treated as any "unknown" specimen while following the specific protocol of the assay being used. This product is intended to be used by healthcare professionals as an integral part of good laboratory practices.

3. Special conditions for use statement(s):

   For Prescription Use

4. Special instrument requirements:

   N/A

I. Device Description:

These products are manufactured in a liquid matrix solution prepared with negative human urine, chemicals and preservatives. The positive control is spiked with 200 - 400 mIU/mL of Human Chorionic Gonadotropin in a urine matrix.

Human source material was tested by FDA approved methods and found negative for HIV 1, HBV and HCV

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bio-Rad Liquichek™ Urinalysis Control and qUAntity® Plus Control System

2. Predicate 510(k) number(s):

   k965171 and k031231, respectively.

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Form	Liquid	Liquid
Matrix	Urine	Urine
Storage	Shelf life 2-8ºC until expiration date	Shelf life 2-8ºC until expiration date

Differences		
Item	Device	Predicate
Analyte	hCG	Specific Gravity, pH, Leukocytes, Nitrite, Protein, Glucose, Ketones, Urobilinogen, Bilirubin, Hemoglobin and hCG

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

Not applicable. This submission is for clearance of control material.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

No traceability indicated.

Chorionic Gonadotropin human is a purchased product which has a known concentration. To produce the positive control a calculation is performed by Biochemical to determine the amount of product needed to spike negative urine to obtain a target range between 200 and 400 mIU and tested by radioimmunoassay. Subsequent testing is performed qualitatively.

New lots of material are run against released lots as well as against other existing controls in the market. Aliquots are stored at room and refrigerator temperature. Testing is performed on day one and day 31. Room temperature samples are used to check for cloudiness that would occur if the batch is contamination or not properly preserved. Upon acceptance of the master batch the control is dispensed into vials and sampled according to GMP.

Stability:

Real time stability studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The stability is listed below:

Open vial stability is 31 days at 18-25ºC or 2-8ºC

Closed vial stability is two years at 2-8º or 31 days at 18-25ºC

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Not applicable

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

*b. Clinical specificity**:***

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Proposed Labeling:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.